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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,015	07/16/2003	Isador H. Lieberman	CCF-6387	9116
26294 7590 03/30/2007 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700			EXAMINER	
			SHAFFER, RICHARD R	
CLEVEVLANI	CLEVEVLAND, OH 44114		ART UNIT	PAPER NUMBER
			3733	
·				
SHORTENED STATUTORY	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS 03/30/2007		PAP	PER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
Office Action Comments	10/621,015	LIEBERMAN, ISADOR H.				
Office Action Summary	Examiner	Art Unit				
	Richard R. Shaffer	3733				
The MAILING DATE of this communication appeariod for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION (6(a). In no event, however, may a reply be time till apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE!	l. lely filed the mailing date of this communication.  D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 22 Ja	nuary 2007.					
,	action is non-final.					
3) Since this application is in condition for allowan	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	33 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-7,9,10,12,13,15-33 and 35-54</u> is/are pending in the application.  4a) Of the above claim(s) <u>See Continuation Sheet</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,2,6,7,17,21,24,30,33,36,53 and 54</u> is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correcti						
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).				
<ol> <li>Certified copies of the priority documents</li> </ol>	s have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application						
Paper No(s)/Mail Date	6) Other:	,				
Patent and Trademark Office		·				

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-5,9,10,12,13,15,16,18-20,22,23,25-32,35 and 37-52.

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#### **DETAILED ACTION**

#### Terminal Disclaimer

The terminal disclaimer filed on January 22<sup>nd</sup>, 2007 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the patents previously cited for double patenting has been reviewed and is accepted. The terminal disclaimer has been recorded.

### Specification

The amendment to the title filed on January 22<sup>nd</sup>, 2007 is acknowledged and accepted by the examiner. The corresponding objection is hereby withdrawn.

## Claim Rejections - 35 USC § 101

The amendments to the claims filed on January 22<sup>nd</sup>, 2007 are acknowledged and accepted by the examiner. The corresponding rejections under 35 U.S.C. 101 are hereby withdrawn.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 7, 17, 21, 24, 30, 33, 36, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman (US Patent 5,728,116) in view of Bolduc et al (US Patent 5,964,772).

Rosenman discloses a device (Figures 1-19) comprising: a spike (50); a platform (20) having a cylindrical side surface connecting a first (30) and second (40) opposite surfaces; and a sleeve (Column 5, Line 66 through Column 6, Line 3 and opvious to provide a cannula when performing endoscopy: Column 1, Lines 60-67).

Boldue et al teach (Column 7, Lines 30-34) that employing a double helix, the fastener has increased retentive strength as well as balancing the fastener during insertion. It would have been obvious to one having ordinary skill in the art to provide a second helical spike to the device of Rosenman in order to increase retention as well as stabilize the device during implantation.

The resultant device would then have two helical spikes with proximal/connecting portion (20) and distal ends/tip portion (58) and an intermediate portion in-between; the helical spikes having a solid cross-section of cylindrical shape (Column 6, Lines 9-11) and constant diameter (see Figures 1-3).

In regard to limitations for intended use, the device is inherently capable of being inserted into bone to perform the functional language claimed.

### Response to Arguments

Applicant's arguments with respect to claims 1, 2, 6, 7, 17, 21, 24, 30, 33, 36, 53 and 54 have been considered but are moot in view of the new ground(s) of rejection.

# Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**Art Unit: 3733** 

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Richard Shaffer March 28<sup>th</sup>, 2007

Aichard Shaffer

EDUARDO C'ROBERT SUPERVISORY PATENT EXAMINER